K012520

Cardiac Assist Devices, Inc.
11000 Cedar Avenue, Suite 451
Cleveland, Ohio 44106
Phone: (216) 791-2234
Fax: (216) 791-2234

MAR 2 7 2002

510(k) Summary

[1] Submitter's Information:

Cardiac Assist Devices, Inc.
11000 Cedar Avenue, Suit 451
Cleveland, Ohio 44106
Phone: (216) 791-2234
Fax: (216) 791-2234
E-mail: cardiacassist@aol.com

Contact Person: Rassoll Rashidi, President

Date Summary Prepared: 7-1-2001

[2] Device Names:

Proprietary Device Name: Gyro-Tip Lariat Deflectable Loop Mapping Catheter

Classification name: Diagnostic Electrophysiology catheter

Common Device Name: Electrode Recording Probe

[3] Device Classification:

Class II

[4] Predicate Devices:

- Gyro Tip EP Catheter, Delta Series. **K955847**
- Cordis Webster A20 Diagnostic Deflectable Tip Catheter, **K953768**
- Cordis Webster T20 Diagnostic Deflectable Tip Catheter, **K953663**

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510(k) Summary (continue)

[5] Device Description:

The **Gyro-Tip Lariat Deflectable Loop Mapping Catheter** of Cardiac Assist Devices, Inc. has been designed and developed as a diagnostic catheter for electrophysiological mapping of cardiac structures. The catheter has a braided outer tube that exhibits similar torsional stiffness, under a clockwise and counterclockwise-applied torque directions, to those of the named predicate devices. The distal portion of the subject catheter has up to 20 platinum electrodes that offer radiopacity under fluoroscopy for the required visibility during the cardiac electrophysiology mapping procedures. The accessory cables used to connect the subject device to a recorder/monitor comply with Section 12A of the Underwriters Laboratories UL 544 Standard for safety.

A schematic view of the Gyro-Tip Lariat Deflectable Loop Mapping Catheter is shown in Figure 1.

[6] Indication for Use:

Gyro-Tip lariat Deflectable Loop Mapping Catheter is indicated for multi electrode electrophysiological mapping, recording and/or temporary stimulation, of cardiac structures along circumferential paths.

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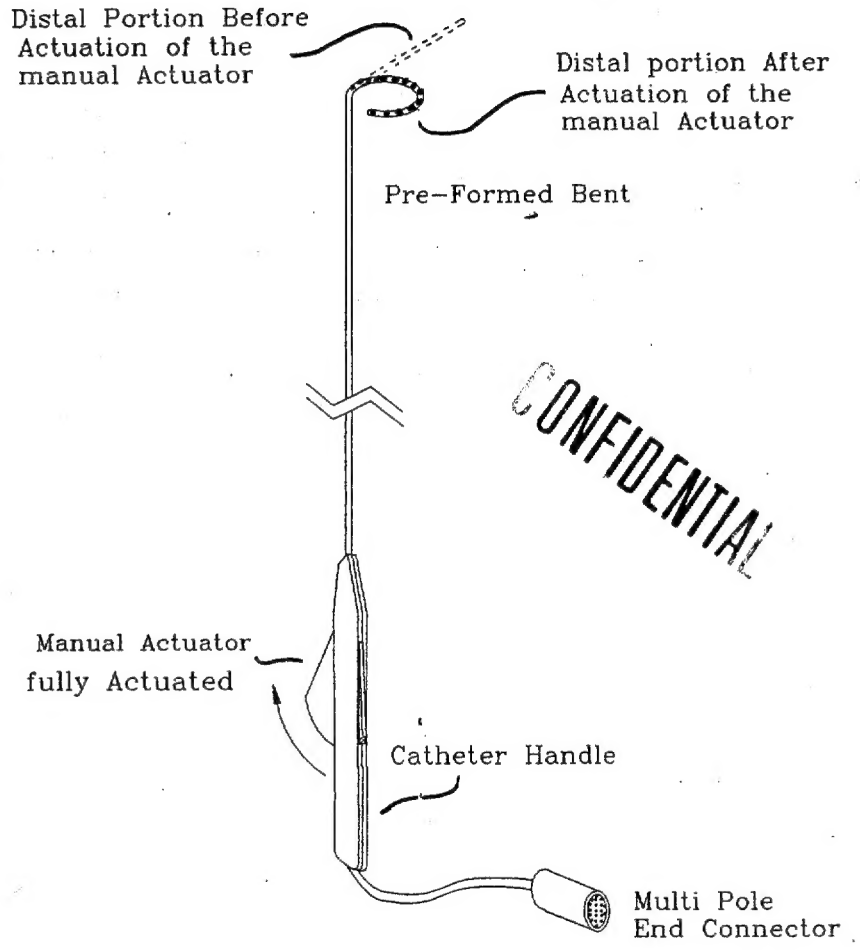

Figure 1
Schematic View of the
Gyro Tip Lariat Deflectable Loop Mapping Catheter

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510(k) Summary (continue)

[7] Technological Characteristics of the Subject Device:

The Gyro-Tip Lariat Deflectable Loop Mapping Catheter is technologically similar to the primary named predicate device, namely the Gyro Tip EP catheter of Cardiac Assist Devices, Inc. that is cleared for marketing under **K955847**. The subject device has more platinum electrodes (up to 20 electrodes) at its distal portion compared to the primary predicate device that has 4 electrodes. This total number of electrodes is however the same as the number of electrodes of the secondary predicate devices that are cleared for marketing under **K953768** (Cordis Webster A20 Diagnostic Deflectable Tip Catheter) and **K953663** (Cordis Webster T20 Diagnostic Deflectable Tip Catheter). Each of these secondary predicate devices has 20 electrodes at its distal portion.

The distal portion of the subject device has a pre-formed bend at its distal portion. This pre-formed bend causes formation of a deflectable loop at the catheter's distal portion in response to the actuation of the steering mechanism located in the catheter handle of the subject device. The steering mechanism of the subject device is exactly similar to the steering mechanism of the primary predicate device, namely the Gyro Tip EP Catheter of Cardiac Assist Devices, Inc. The actuating wires that transmit the actuation forces from the steering mechanism of the catheter handle to the distal portion of the subject device are stainless steel wires having generally circular cross-section with a diameter in the order of 0.012". These actuating wires are the same as the actuating wires of the primary predicated device (cleared under **K955847**). The distal portion of the actuating wires of the subject device has rectangular cross-section, having the same effective cross-sectional area as that of the circular cross-section portion. This better determines the plane of loop formation at the distal portion of the subject device. The geometric plane, in which the distal loop of the subject device is formed, upon the manual actuation of the steering mechanism, is generally perpendicular to the elongated shaft of the catheter. Therefore the subject device can assume a "halo-shaped" configuration at its distal portion, similar to the "halo-shaped" configuration of the distal portion of the secondary predicate device, namely Cordis Webster T20 Diagnostic Deflectable Tip Catheter that is cleared under **K953663.**

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510(k) Summary (continue)

[7] Technological Characteristics of the Subject Device (continued):

The halo-shaped configuration of the distal portion of the subject device, and the process of assuming this final halo-shaped configuration, in response to the manual actuation of its steering mechanism, has shown to be safe and effective through a series of non-clinical testing. The descriptions and results of these tests are included in **Appendices A , B,** and **C** of this 510K, with a brief discussion presented next.

[8] Brief Discussion of the Non-Clinical Tests:

The subject device, (The Gyro-Tip Lariat Deflectable Loop Mapping Catheter) has gone under a series of non-clinical testing in order to determine its performance characteristics as they relate to its safety and effectiveness. These tests were performed according to FDA's "Electrode Recoding Catheter preliminary Guidance". The results of these non-clinical tests were compared to results of the same tests on predicate devices. **The comparison of the results indicates that the subject device is as safe, and as effective, as the named predicate devices.**

[9] Conclusion Drawn From Non-Clinical and Clinical Tests:

The results of the non-clinical tests, presented in **Appendices A, B, C, D,** and **E** of this 510(k) indicates that the subject device (The Gyro-Tip Lariat Deflectable Loop Mapping Catheter) performs as well as the named predicate devices, and any minute differences in the test results are not significant to influence the safety and effectiveness of the subject device. **Therefore, Cardiac Assist Devices, Inc. presents the Gyro-Tip Lariat Deflectable Loop Mapping Catheter as substantially equivalent to the named predicate devices in this 510(k).**

[10] Additional Information:

Available upon request

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 7 2002

Mr. Rassoll Rashidi
President
Cardiac Assist Devices, Inc.
11000 Cedar Avenue, Suite 451
Cleveland, OH 44106-3052

Re: K012520
Trade Name: Gyro-Tip Lariat Deflectable Loop Mapping Catheter
Regulation Number: 21 CFR 870.1220
Regulation Name: Electrode Recording Catheter
Regulatory Class: Class II (two)
Product Code: DRF
Dated: December 20, 2001
Received: December 27, 2001

Dear Mr. Rashidi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

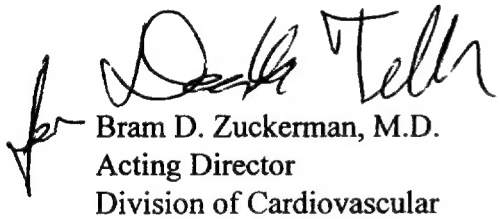
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): **K012520**

Device Name: **Gyro Tip Lariat Deflectable Loop Mapping Catheter**

Indications For Use:

The Gyro Tip Lariat Deflectable Loop Mapping Catheter is indicated for multi-electrode electrophysiological mapping, recording, and or temporary stimulation of cardiac structure.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K012520
EMellis

Prescription Use ✓ OR Over-The-Counter Use___
(Per 21 CFR 801.109)

(Optional Format 1-2-96)